INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR DEFERRAL OF NEW PROTOCOL
TO ANOTHER INSTITUTIONAL IRB

Date Rec'd in HSO:_____

Instructions: Use this form when submitting a request for deferral of a new protocol to another institution's IRB. Please submit this form electronically along with the protocol and any supporting documents to your CIO human subjects contact. However, if submitting hard copies, please send the original request form with one copy of all documents to the CIO designated staff official. Consecutively number **ALL** pages, beginning with the title page of the protocol, followed by any consent form(s) and ancillary documents. Complete all applicable items or the form will be returned.
OMB Reminder: Please note that you are responsible for obtaining OMB clearance on Federally sponsored information collections. An IRB approval of **or** an exemption from IRB review is unrelated to requirements for OMB clearance under the Paperwork Reduction Act. For more information on whether there are legal requirements for your study to go through the OMB clearance process, please contact your CIO's OMB coordinator or OPPE clearance staff.

Date Submitted by Investigator: _____

PROTOCOL NO: _____
(For Human Subjects Office Use)

Title of Protocol: _____
_____

Proposed Dates for Project to Begin: _____ End: _____

Name of Primary CDC Contact (PC) and Degrees: _____

Scientific Ethics Verification No.: _____ Telephone:_____ Fax: _____
CIO: _____ **Division**: _____ **MS**: _____ User ID (UID): _____

List all CDC Co-investigators below (list CDC Principal Investigator (PI) in #1 if different from the PC indicated above). If PI is indicated her, insert PI before name (use supplemental page if number of investigators is > than 2):

1._____ *Scientific Ethics* Verification No.: _____
2. _____ *Scientific Ethics* Verification No.: _____
3. _____ *Scientific Ethics* Verification No.: _____

Name, degrees, and affiliation of Primary Contact (PC)/Principal Investigator (PI) with outside institution:

_____
Telephone: _____ Fax: _____ Email Address: _____

Name of outside institution:

_____
Institution protocol Identification No.: _____ (Provide title if different from CDC title):
_____

Name and degrees of the IRB manager at institution with IRB to contact regarding this request:
_____
Telephone: _____ Fax: _____ Email Address: _____

Complete Mailing Address for institution: _____
_____

FUNDING MECHANISM: Insert appropriate code from list below. If funded, include Procurement & Grants Office funding No. **Grant = G** **Cooperative Agreemt = CA** **Contract = C** **Purchase Order = PO** **Interagency Agreemt = IAA** **Memorandum of Understanding = MOU** **CDC only = CDC** **Collaborative = COL**	**LOCATION OF RESEARCH (Use additional sheets if necessary):** **[ ] U.S. or its territories and/or** **[ ] Foreign countries**		
	List All Collaborating Institutions by Full Name, City, State, and/or Country	**OHRP Assurance No:**	**IRB/IEC Approval attached/ pending**
1.			
2.			
3.			

STUDY POPULATION (If an international study, provide race/ethnicity of subjects by estimated percentages):

Estimated Number of Subjects:_____

Gender Distribution:
_____ % Male
_____ % Female

Race/Ethnicity Distribution for Domestic Studies:
_____ % American Indian or Alaskan Native
_____ % Asian or Pacific Islander:
_____ % Black or African American; not of Hispanic Origin
_____ % Hispanic
_____ % White, not of Hispanic Origin

[ ] Study includes members of Vulnerable Populations (Check all that apply):

[ ] Pregnant women and/or fetuses as SPECIFIC targets group (Ref: 45CFR46, Subpart B)

[ ] Children 17 years of age or under(Ref: 45CFR46, Subpart D)

[ ] Requesting waiver of parental permission

[ ] Mentally disabled

[ ] Economically or educationally disadvantaged

[ ] Prisoners (Ref: 45CFR46, Subpart C)

1. CRITERIA FOR RELIANCE ON ANOTHER IRB (check and provide justification for all that apply)
Deferring institution's role is limited to the following:

[ ] The principal investigator is not an employee, contractor, visiting scientist or fellow of deferring institution. This policy does not apply to an employee who is assigned to another agency and who functions as an employee of that agency and lists his/her affiliation with the agency being deferred to:

Provide title/position of principal investigator:

_____

[ ] Investigator(s) from deferring institution does not have any direct interaction with study participants or possess or have access to any identifiable data from the study.

Explain how investigator from deferring institution meets this criteria:

_____

[ ] The study is being deferred to an outside organization that has an OHRP approved FederalWide or Multiple Project Assurance (FWA or MPA) and that institution's IRB has reviewed and approved the study and their institution is responsible for participant recruitment.

How will participants be recruited: _____

_____

[ ] The study involves no more than minimal risk and does not address a controversial topic. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Controversial topic means a sensitive topic such as illegal behaviors, sexual behavior practices, or psychiatric illness; involves a vulnerable population as defined in 45 CFR 46; or is of particular interest to the DHHS or Congress.

Study is minimal risk because: _____

[ ] The study has not yet begun. Meaning no involvement with the human subjects or any personal identifiable information has begun.

Explain status of the study (i.e. study is still in the planning and/or preparation phase): _____

_____

2. DESCRIBE CDC'S ROLE IN THE STUDY, INCLUDING PROTOCOL DEVELOPMENT:

_____
_____
_____

3. COPIES OF ALL OF THE FOLLOWING ITEMS ARE REQUIRED TO BE SUBMITTED WITH THE REQUEST FOR DEFERRAL. COPIES MUST BE RECEIVED BY HUMAN SUBJECTS ACTIVITY BEFORE REQUEST WILL BE APPROVED (check mark all that are attached and give written explanation for any item not attached)**:**

[ ] IRB approved Protocol

[ ] IRB approved consent forms

[ ] IRB approval letter/report

[ ] IRB minutes pertaining to this protocol

DATA CONFIDENTIALITY INFORMATION (CIRCLE) **REFERENCE(S):**

Is there an Assurance of Confidentiality to cover this project by the institution with the IRB?	YES	NO	Applied For	N/A	§ 308(d) PHS Act
Does the local site(s) have a Certificate of Confidentiality to cover this project?	YES	NO	Applied For	N/A	§301(d) PHS Act

Approvals (Signature and Position Title):	**Date:**	**Remarks:**
Branch Chief:		
Division Director:		
CIO Human Subjects Contact:		